

April 23, 1997

Elizabeth A. Yetley, Ph.D. HFS-450
Acting Director
Office of Special Nutritionals
Center for Food Safety and Applied Nutritionals
FOOD AND DRUG ADMINISTRATION
200 "C" Street, SW, Room 2804C
Washington, DC 20204

0134 '97 SEP 19 P1:42

Dear Dr. Yetley:

Pursuant to section 6 of the Dietary Supplement Health and Education Act of 1994 codified at 21 U.S.C. §343(r)(6), Metabolic Technologies, Inc., Northwestern University/ Evanston Research Park, 1840 Oak Avenue, Evanston, Illinois, hereby notifies the Food and Drug Administration that it is making a statement of nutritional support for its dietary supplement marketed under the brand name Metacalm[®]-S.

Metacalm[®]-S is a dietary supplement formulated specifically to give nutritional support to those who choose to quit smoking. This dietary supplement is not a smoking deterrent, and no claims such as those described in 21 CFR §310.544 will be made for the product. It will not make a person stop smoking, and does not mitigate, cure, treat or prevent disease. Metacalm[®]-S tablets supply minerals, vitamins, amino acids and herbs in a synergistic form to affect the structure and function of the cells of the body and permit them to return to a more normal metabolic state once the ingestion of nicotine has ceased.

Cells of the Body are overwhelmed by chemicals in cigarette smoke

The more than 100 trillion cells of the body normally work together for survival of the organism. Over a period of time, the stress of tobacco smoke and its 4000 chemicals overwhelm cellular controls resulting in altered metabolic pathways. The two method patents [5,308,827 and 5,332,579] issued in 1994 teach that substance abuse alters these metabolic pathways. The physiological cravings associated with substance addictions appear in part to be a generalized response of the organism to one or more nutritional deficiencies or metabolic compromises associated with addictive states.

Mechanisms of delivery of nutrients to cells

The delivery of these nutrients to the cells of the body occur via uptake in the blood and lymph in cooperation with homeostasis and normalized cellular organization as outlined in the opening two chapters of Textbook of Medical Physiology, Arthur Guyton, 1996. Specialized

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cellular membranes allow specific exchanges of blood and lymph circulation of nutrients to cells and removal of waste products. The cells of lungs, liver, heart and brain are a few of the many organs directly affected and often overwhelmed by the effects of cigarette smoke over time.

Utilization of nutrients by cells

Specialized structures within each cell, such as mitochondria, golgi bodies, ribosomes and other subcellular structures function to effect nutritional metabolic cellular change. Mechanisms of exchange for tissues, organs and organ systems and the biodynamic metabolic processes of their individual cellular structures follow the laws of biochemistry and intermediary metabolism including the krebs cycle. [Biochemistry, Luber Stryer, 1988. Flow Chart of Amino Acid Metabolism, John Pangbom. 1987. Intermediary Metabolism, PL Biochemicals, 1972. Biochemical Pathways, Gerhard Michal, Boehringer Mannheim Biochemicals, 3rd Ed. 1992]

Metacalm®-S delivers nutrients as metabolic substrate building blocks

Metacalm®-S tablets deliver nutritional metabolic substrates to the body cells permitting human tissues to begin the process of repair, rehabilitation, normalization and optimization of cellular and subcellular structures and functions bringing about the eventual return toward health.

Cells work as designed via structure and function in the repair, rehabilitation, normalization and optimization to bring about a return to cellular health, the restoration of metabolic balance and cellular homeostasis

These subcellular processes are dependent upon the individual making a determination to quit smoking. Once the individual is no longer ingesting nicotine, this dietary supplement works with the metabolic processes of the human body in restoring the structure and functions of cells. These metabolic nutritional substrates permit the cells of the body to recover naturally from many of the effects of chemicals in cigarette smoke. After taking Metacalm®-S tablets for an appropriate period of time, the cells effect repair and return the body toward health. In spite of the cellular burdens presented by tobacco smoke, this dietary supplement, via nutritional support, aids the cells in restoring homeostasis, metabolic balance and cellular health.

STATEMENT OF NUTRITIONAL SUPPORT

1. Description of the Role of Metacalm®-S

Substance abuse, including smoking, affects cellular metabolism throughout the human body. Metacalm®-S assists the cellular metabolic needs of a person experiencing nicotine withdrawal. The nutrients in Metacalm®-S cooperate synergistically in enhancing cellular metabolic pathways and assist in the normalization of cellular functions and optimization of cellular health.

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2. Metacalm®-S Composition and Statement of Mechanics by which Ingredients Act to Maintain Bodily Function

Metacalm®-S is comprised of vitamins, mineral and amino acids, all of which are generally recognized as safe. The product also contains two herbs, valerian root and echinacea root.

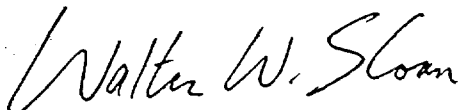
The product is comprised of appropriate amounts of at least one enzyme activating substance and at least one enzyme cofactor. The enzyme activating substance stimulates enzyme catalysis of at least one cellular chemical reaction occurring in the human organism, while the enzyme co-factor substantially regulates the cellular chemical reaction at an approximately normal metabolic rate.

Metacalm®-S is also comprised of sufficient amounts of at least one amino acid and at least one herbal antispasmodic substance. The amino acid produces an enzyme that acts as a catalyst for the normalized cellular chemical reaction, while the herbal antispasmodic substance normalizes the vegetative function of the cellular chemical reaction. By supplying the sufficient amounts of these substances, a human organism can normalize cellular activity structures and functions.

If you have any questions regarding this notification, please contact us. Two copies of the notice are enclosed.

Sincerely,

Metabolic Technologies, Inc.



Walter W. Sloan
President and CEO

cc: George M. Burditt, Burditt & Radzius